Automated Insulin Delivery “In The Wild"

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Objective

A dosing algorithm is Not Enough!

The objective of this research is to improve the safety of automated insulin delivery when encountering everyday system incidents including: sensor changes/ calibrations, system startup/shutdown, Continuous Glucose Monitor (CGM) and insulin pump communication errors, infusion set changes, insulin refills and battery changes.

Method

Our new autodosing mode control (ADMC) module allows closed-loop insulin dosing only when interfacing subsystems are operating normally. The ADMC suspends insulin dosing and reverts to the user’s preprogrammed basal when it detects something is wrong. Automated insulin delivery resumes when problems are resolved.

Table 1:

Study ID	Interruption type	# interruptions
301V2, 304V1, 304V1, 302V3, 302V4, 303V2, 303V3, 304V1, 305V2, 305V4	CGM signal interuption	18
302V4, 303V3, 304V1, 305V2, 305V3	Pump communications interuption	20
301V1, 305V3	APS platform user error	2
	TOTAL	40

Forty (40) system incidents (Table 1), resulting in missed automated insulin doses, occurred in 17 Daily Living clinical studies in the CRC. In each case, because the ADMC was not yet implemented, the on site engineer had to intervene and manually restore closed-loop dosing.

Results

New software in the Dose Safety Controller monitors the status of the CGM and insulin pump in real-time, and enables / disables closed loop operation accordingly. The system mode logic is shown in figure 1. The values of Boolean variables *CgmSysOpNormal* and *PumpSysOpNormal* are calculated every 5 minutes.

CgmSysOpNormal is a function of the CGM system communications heartbeat, CGM system status bits and the CGM time stamp values.
PumpSysOpNormal is calculated based on the pump communications heartbeat, and pump system status bits.

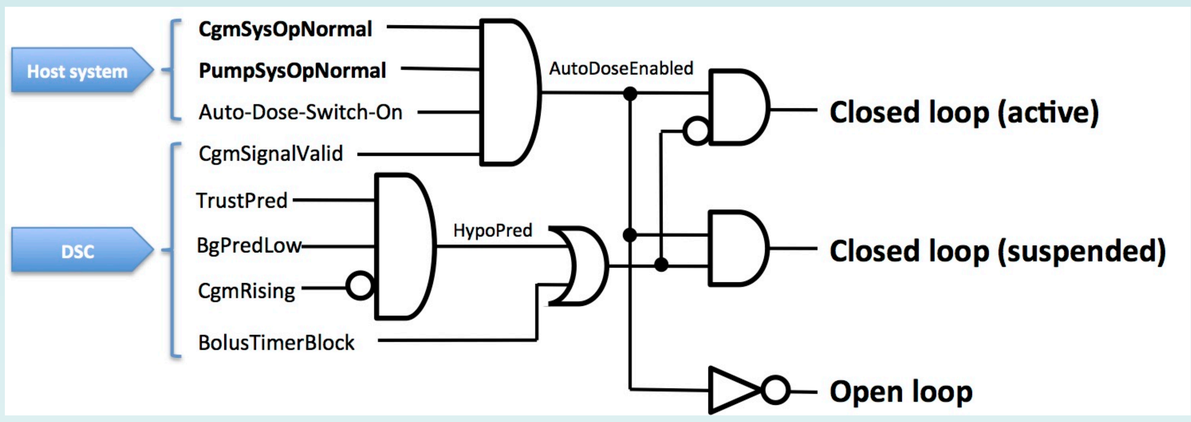

Figure 1:

We analyzed the 40 system incidents given the ADMC mode logic and concluded that 38 (95%) of the incidents would have been detected and the closed loop dosing temporarily suspended.
The remaining 2 incidents were caused by operator error and not detectable by the ADMC.

Conclusion

The retrospective analysis of system incidents in prior clinical studies showed that the ADMC module would have detected 95% of the system faults and temporarily suspended fuzzy logic dosing module (FLDM) dosing. The FLDM, in conjunction with the ADMC, will safely administer automated insulin delivery “in the wild".

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